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Section 5 - 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

MAY 24 2012

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Summary Prepared: October 28, 2011

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Name of Device:
Trade Name(s): Praezis Plus 3.1
Classification Name: Planning system/Stereotaxic instrument
Classification: 21 C.F.R §882.4560
Panel: Neurological
Product Code: HAW

Predicate Device:

Leibinger Stereoplan Plus Stereotactic Treatment Planning Software Package, Leibinger LP (K946033)

Intended Use/Indications for Use

The Praezis Plus system is computer software intended to be used in planning intracranial stereotactic surgeries such as biopsies and treatment of lesions. The intended user of Praezis Plus is a medical doctor - neurosurgeon.

Technological Characteristics

Praezis Plus is a software tool intended to help the surgeon plan stereotactic treatments. It enables the user to select optimally fitting stereotactic trajectory positions by digitizing the entry (trephination) and target points of the trajectory. If both points define

a trajectory which can be set on the operating device, the corresponding device settings are calculated and displayed in the trajectory window. Any trajectory can be defined and displayed in CT and/or MRI slices or reconstructions or angiographic images if they are available. Trajectories are always stored in stereotactic coordinates and can be digitized and displayed in available patient's modalities (CT, MR or Angiographic). The software can project the selected trajectory to any slices or sections and generate surgeon's eye views. For any possible needle position, the angle settings for either the Riechert/Mundinger (RM) or Zamorano/Dujovny (ZD) stereotactic operating devices can be displayed.

Praezis Plus supports the transfer of stereotactic coordinates between angiographic, CT and MR images. Regions of Interest ("ROIs") and Volumes of Interest ("VOIs") can be defined, transferred and displayed between angiographic, CT and MR images. Their area and volume can be calculated.

Global stereotactical transformation is available to improve the planning. Image fusion, based on various methods of correlation, allows a combination of valuable information from different modalities. Several types of reconstructed sections such as arbitrary, along and perpendicular to trajectory together with 3D reconstructions are also available.

It is possible to print out all the images and protocols and together with patient data archive them on a CD.

The output from Praezis Plus is a printed stereotactical plan defining the trajectory and the setup of the stereotactical device. The treatment plans may be used to administer treatments after review and approval by the neurosurgeon.

See the table below for a detailed comparison of the technological characteristics of Praezis Plus and the predicate device.

Characteristic	**Praezis Plus**	**Stereoplan Plus** (K946033)
Product Code		HAW
Classification Regulation	21 CFR 882.4560	21 CFR 882.4560
Indication for Use	The Praezis Plus system is computer software intended to be used in planning intracranial stereotactic surgeries such as biopsies and treatment of lesions. The intended user of Praezis Plus is a medical doctor - neurosurgeon.	The Stereoplan Plus is intended to be used in planning stereotactic treatment of intracerebral lesions. Specifically, the Stereoplan Plus system is intended for planning stereotactic punctures. This indication for use is cleared for the predicate device the STP Complete Module Set, also developed and marketed by Leibinger under K892425/D.
Brief Device Description	Praezis Plus is a software tool intended to help the surgeon plan stereotactic treatments. It enables the user to select optimally fitting stereotactic trajectory positions by digitizing the entry (trephination) and target points of the trajectory. If both points define a trajectory which can be set on the operating device, the corresponding device settings are calculated and displayed in the trajectory window. Any trajectory can be defined and displayed in CT and/or MRI slices or reconstructions or angiographic images if they are available. Trajectories are always stored in stereotactic coordinates and can be digitized and displayed in available patient's modalities (CT, MR or Angiographic). The software can project the selected trajectory to any slices or sections and generate surgeon's eye views. For any possible needle position, the angle settings for either the Riechert/Mundinger (RM) or Zamorano/Dujovny (ZD) stereotactic operating devices can be displayed.	Stereoplan Plus is a software tool intended to help the surgeon plan stereotactic treatments. It enables the user to select optimally fitting stereotactic catheter positions by digitizing the entry (trephination) and target points of the catheter needle. If both points define a needle which can be set on the operating device, the corresponding angles are calculated and displayed in the needle window. Any needle can be defined and displayed in CT slices or sections or angiographic images if they are available. Needles are always stored in stereotactic coordinates and can be digitized and displayed in any space of patient's images (CT, MR or Angiographic). The software can project the selected needle to any slices or sections and generate surgeon's eye views. For any possible needle position, the angle settings for either the Riechert/Mundinger or Zamorano/Dujovny stereotactic operating devices can be displayed. Stereoplan Plus supports the transfer of stereotactic

Characteristic	**Praezis Plus**	**Stereoplan Plus** (K946033)
	Praezis Plus supports the transfer of stereotactic coordinates between angiographic, CT and MR images. Regions of Interest ("ROIs") and Volumes of Interest ("VOIs") can be defined, transferred and displayed between angiographic, CT and MR images. Their area and volume can be calculated. Global stereotactical transformation is available to improve the planning. Image fusion, based on various methods of correlation, allows a combination of valuable information from different modalities. Several types of reconstructed sections such as arbitrary, along and perpendicular to trajectory together with 3D reconstructions are also available. It is possible to print out all the images and protocols and together with patient data archive them on a CD. The output from Praezis Plus is a printed stereotactical plan defining the trajectory and the setup of the stereotactical device. The treatment plans may be used to administer treatments after review and approval by the neurosurgeon.	coordinates between angiographic, CT and MR images. Regions of Interest ("ROIs") and Volumes of Interest ("VOIs") can be defined, transferred and displayed between angiographic, CT and MR images. Their area and volume can be calculated. There are two major components of the Stereoplan Plus System: the hardware utilized to position and restraint the patient's head; and the software used to position the hardware.
Intended User	Neurosurgeon	Neurosurgeon
Operating principle	Stereotactic planning software	Stereotactic planning software
Stand alone software application	Yes	Yes

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Characteristic	**Praezis Plus**	**Stereoplan Plus** (K946033)
Software features	• DICOM image loading • Image presentation • Stereotactical image registration • Multimodal registration • Automatic multimodal registration • Atlas registration • Image reconstructions • Image fusion • 3D reconstructions • Contouring the patient – create ROIs • Trajectory planning • Trajectory planning functional • Stereotactical device calculation • Print images • Registrations archived in private groups of DICOM files • Image reslicing • DICOM export	• DICOM image loading • Image presentation • Stereotactical image registration • Identity based Multimodal registration on the stereotactical ring • Atlas registration • Image reconstructions • 3D reconstructions • Contouring the patient – create ROIs • Trajectory planning • Trajectory planning functional • Stereotactical device calculation • Print images • Registrations archived in private groups of DICOM files

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Consensus Standards
Praezis Plus complies with the following recognized consensus standards:

- ISO 14971:2007 Medical devices - Application of risk management to medical devices (FDA Recognition number 5-40)
- NEMA PS 3.1-3.18 2008 Digital Imaging and Communications in Medicine (DICOM) (FDA Recognition number 12-183)
- EN 62304 EN 62304:2006 Medical device software – Software life cycle processes (FDA Recognition number 13-8)

Performance Data

System Validation

The system validation of Praezis Plus was performed by manufacturer during the validation phase. The relevant features of the pre-released product were tested according to the test plan (a set of test cases) using the test data and the results were recorded to the validation protocol.
Some of the tests were designed as benchmark tests to compare validated system to the benchmark system. All the reference values were measured digitally using the benchmark software (Stereoplan Plus), therefore the reference values were considered to be ideally exact. The measured values were taken the same way; therefore absolute equality would be expected. The allowed inaccuracy was enabled only to accept possible cumulative error resulting from limited resolution of imaging and pointing devices. If no tolerance was allowed then only exactly equal results were allowed.
These benchmark test results demonstrate that the computation accuracy of Praezis Plus is as good as Stereoplan Plus. The test results support the safe and effective use of the Praezis Plus to guide a device to a brain target with an error less than 1mm.

Beta Site Testing

The beta site testing of Praezis Plus was conducted at two hospitals:
1) Beth Israel Deaconess Medical Center - Harvard Medical School, Boston and
2) University of Chicago Medical Center - Section Of Neurosurgery, Chicago.
The basic concept of the beta site testing method was to compare the currently validating version of the product with the bench mark device (Stereoplan Plus) in the near-clinic (virtual) environment. It means all the existing relevant procedures in the hospital were followed in addition to using the features of Praezis Plus software. Thus, the product was not used for reference during the making a diagnosis – it was used in parallel path for result comparison only.
The conclusion of the both testing was that Praezis Plus fulfills the declared requirements and is consistently safe and accurate comparing to the bench mark device, thus suitable for use in the scope of its declared intended use.

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Substantial Equivalence

Praezis Plus and its predicate device are stand-alone software systems that are equivalent in indications for use and technology.

Praezis Plus supports all of the features of the Stereoplan Plus (including DICOM image loading, image presentation, reconstruction contouring, 3D reconstruction, stereotactical images, and atlas registration; trajectory planning, and stereotactical device calculation). Moreover, Praezis Plus supports automatic multimodal registration and image fusion; image reslicing, and DICOM export.

Praezis Plus is as safe and effective as the Stereoplan Plus. Praezis Plus has the same intended use and similar indications, technological characteristics. The minor technological differences between Praezis Plus and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate Praezis Plus is as safe and effective as the predicate device. Thus, Praezis Plus is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

TatraMed spol. s.r.o.
c/o Ms. Caroline Tontini
Project Manager
Emergo Group
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Austin, TX 78701

MAY 24 2012

Re: K110644
Trade/Device Name: Praezis Plus
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: May 21, 2012
Received: May 22, 2012

Dear Ms. Tontini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110644

Device Name: Praezis Plus

Indications for Use:
The Praezis Plus system is computer software intended to be used in planning intracranial stereotactic surgeries such as biopsies and treatment of lesions. The intended user of Praezis Plus is a medical doctor - neurosurgeon.

Prescription Use ___XX____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K110644

Prescription Use X
(Per 21 CFR 801.109)